UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,498	10/11/2005	Taliesin John Golesworthy	4393-120 US	5329

26817 7590 03/10/2008
MATHEWS, SHEPHERD, MCKAY, & BRUNEAU, P.A.
29 THANET ROAD, SUITE 201
PRINCETON, NJ 08540

EXAMINER	
NGUYEN, TUAN VAN	

ART UNIT	PAPER NUMBER
3731	

MAIL DATE	DELIVERY MODE
03/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/527,498	GOLESWORTHY ET AL.	
	Examiner	Art Unit	
	TUAN V. NGUYEN	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *33* is/are allowed.

6)☒ Claim(s) *1-32 and 34-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-36 are pending in this present application.
2. In previous Office action, claims 1-31, 34 and 36 were examined and rejected and claims 32, 33 and 35 were indicated allowable over prior art of record.

Continued Examination Under 37 CFR 1.114

3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after the final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 15, 2007 has been entered.

Response to Amendment

4. Applicant's arguments filed on October 15, 2007 with respect to rejection of claims 3 and 5 have been fully considered but they are moot in view of the new grounds of rejection.
5. Applicant's arguments filed on October 15, 2007 with respect to rejection of claims 1 and 5 have been fully considered but they are not persuasive. With respect to argument on page 7 of the remarks that Sirhan fails to teach or suggest a stent having a size which morphologically matches the morphological profile of the

blood vessel, such as the ascending aorta and Sirhan also fails to teach or suggest that the stent supports the exterior of the blood vessel in substantially full contact therewith. Examiner respectfully traverses the applicant's remarks: Sirhan clearly discloses the containment 10 for treating vulnerable tissue sites such as aortic aneurysms and organs (see col. 7, lines 5-10) wherein the containment disposed in a condition that the inner diameter of the containment substantially the same the outer diameter of the tissue site (see col. 7, lines 20-35) and Figure 63 shown the containment member substantially full contact with the vessel and only act to contain the vulnerable tissue site minimizing its further growth (see col. 13, lines 1-3), thusly, Sirhan discloses the containment is morphologically matches the morphological profile of the blood vessel and Sirhan containment is capable to matches the morphological profile of the ascending aorta and ventricle muscle as claimed by the applicant.

Allowable Subject Matter

6. Claim 33 is allowable over prior art of record. No combinations of the prior art disclose or fairly suggest all of the limitation of this claim, particularly the steps of embroidering the a woven structure onto shell, especially, the step of removing the shell following completion of the embroidery to provide a stent.

7. The indicated allowability of claims 32 and 35 in previous Office is withdrawn in view of the newly discovered reference(s) to Phillips et al (US 6,899,728). Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. **Claims 1, 2, 4, 5, 6, 7-10, 15, 16, 18-22, and 24-26 is rejected under 35 U.S.C. 102(e) as being anticipated by Sirhan et al (US 6,648,911).**

10. Sirhan et al disclose (see Figs. 3, 10-16, 36-43 and 63) the invention substantially as claimed including a containment member 10 or stent for locations exteriorly of a blood vessel, that can be formed in morphological relationship with a blood vessel, and means for maintaining the stent in relationship with the vessel (col. 7, lines 20-35 and col. 9, lines 35-45), forming the stent from a sleeve of at least two parts, the sleeve being generally of cylindrical form (col. 8, lines 54-65), the sleeve provided with appropriately located recesses or apertures for accommodating other interconnecting arteries (col. 11, lines 50-62), the interconnection of the parts of the sleeve effected by a hinge mechanism with releasable latches provided at the mating edges of the parts (col. 9, lines 35-42), wherein at least one spiral part is adapted in use to locate over and coil around the blood vessel to provide in position the morphological relationship with the blood vessel (col. 6, lines 2-4), and wherein each spiral part is provided with inter-engaging means for connection to

an adjacent part (col. 7, lines 16-20) and the spiral forming an open coil or a closed coil around the blood vessel (col. 9, lines 1-12). Sirhan et al also disclose the inner surface of the stent to be of a smoothness to ensure that no fretting or abrasion occurs and the external surface of the stent is tolerant of other adjacent body parts (Figs. 14-16, the inside surface is shown to be smooth). Sirhan et al further disclose that the material from which the stent is produced is resistant to the effects of electromagnetic fields (col. 6, lines 20-28; plastics are not electromagnetically sensitive), that the stent can be produced from a material that is thermally stable and biocompatible (col. 6, lines 20-28), and that the stent can be produced from any material that is composed of or a mixture of polymeric, metallic, or ceramic (col. 6, lines 20-28). Sirhan et al also disclose that the stent is adjustable in situ (col. 12, lines 4-10).

11. Regarding **claim 5**, Sirhan et al further disclose that there is a base or flange portion adapted for attachment to a main heart structure such that a securement or anchor point is established for the stent, the base or flange portion being adapted for appropriate attachment to the said structure (col. 2, lines 50-56).

12. Regarding **claims 7-10**, Sirhan et al further disclose that the sleeve of the stent is slit longitudinally to allow it to be expanded over the wall of the artery and then to recover its original condition, the sleeve being suitably clampable in position embracing the artery in a morphological relationship (figs. 15A and 15B, notice how the sleeve edges overlap; the edges are created by a longitudinal slit), the clamping is achieved by the application of suitable ties and there are one or more

grooves with the sleeve for receiving and locating the ties (col. 8, lines 25-30), and the clamping can be effected by the insertion of a locking pin extendable through hinge elements provided at the mating edges of the slit in the sleeve (col. 9, lines 35-42).

13. Regarding **claims 20 and 25**, Sirhan et al disclose that the material from which the stent is made from can be a heat shrinks plastic (col. 6, lines 20-25) or a translucent material (col. 6, line 66 -col. 7, line 3).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. **Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al (U.S. 6,648,911).**

17. Due to lack of criticality in the specification, the inter-engaging screw connection was shown to solve no particular problem, serve no particular purpose and provide no additional benefit as opposed to any other means of inter-engaging. Since it has been held that substitute one known element for another to obtain predictable results is old and well known in the art, therefore, it would have been obvious to make the means of interengaging between the spiral stent components be a screw connection because it is capable of working equally as well as a locking pin and hinge elements.

18. **Claims 3, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al (US 6,648,911) in view of Eno et al (US 6,197,050).**

19. Sirhan et al disclose the invention substantially as claimed except for the stent is in the form of a sleeve in at least two parts, the sleeve includes one or more sections of varying form. However, Eno discloses a transmyocardial implant for establishing a blood flow path through a myocardium between a hear chamber and a lumen of a coronary vessel residing on an exterior of the heart (see Summary of The Invention) wherein the implant (see Fig. 3A) is a sleeve that includes one or more sections of varying thickness to conform to the morphological profile of the connecting vessels and compliance with the pulsing of blood through the vessels (col. 3, line 22 to col. 4, line 16). Therefore it would have been obvious to one of

ordinary skill in the art to incorporate the design of the implant having varying thickness as disclosed by Eno into the device of Sirhan so that it too would have the same advantage.

20. **Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al (US 6,648,911) in view of Doorly et al (US 6,554,856).**

21. Sirhan et al disclose the invention substantially as claimed except for the sleeve has an outer and inner casing wherein the outer casing is of more rigid construction that the inner casing and wherein the inner casing is of petal-like form. However, Doorly et al teach (Fig. 2) an outer and inner casing wherein the outer casing is of more rigid construction that the inner casing and wherein the inner casing is of petal-like form 2 (col. 3, lines 56-59). Apparently varying the flexibility of the stent in this manner allows it to have a better conforming capability to achieve a better morphological fit between the implant and vessel. Therefore it would have been obvious to have the inner and outer casings of different rigidities and to have petal like forms to allow a better morphological fit between the stent and vessel.

22. **Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al (US 6,648,911) in view of Kocur et al (US 2002/0103527).**

23. Sirhan et al disclose the invention substantially as claimed except for the stent is made from a material that contains antibiotics gradually releasable in time. However, Kocur et al teach that it is old and well-known in the art for a stent to deliver therapeutic substances such as antibiotics that are gradually releasable

over time. The device of Sirhan et al has already disclosed that it can be made of biodegradable materials that gradually biodegrade over time and a well-known purpose of this is so that therapeutic substances can be released. Therefore it would have been obvious to one of ordinary skill in the art to incorporate the design intended as disclosed by Kocur into the device of Sirhan so that it too would have the same advantage.

24. **Claims 27-31 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al (US 6,648,911) in view of D'Urso (US 6,112,109).**

25. Sirhan et al disclose the invention substantially as claimed except for method of manufacturing a stent for morphologically fitting a blood vessel by the steps of producing a 3D computerized model from a scanned image of the blood vessel and rapid prototyping the computerized 3D model in an appropriate material to provide the stent or a mold for the stent or a precursor thereof for morphologically matching the blood vessel.

26. Regarding **claims 27-29**, however, D'Urso teaches a method of manufacturing a stent for morphologically fitting a blood vessel by the steps of producing a 3D computerized model from a scanned image of the blood vessel and rapid prototyping the computerized 3D model in an appropriate material to provide the stent or a mold for the stent or a precursor thereof for morphologically matching the blood vessel (col. 6, lines 33-54 and col. 9, lines 48-60), that the scanned image is obtained by either MRI, MRA, X-ray CT, or 3D pulsed Doppler (col. 5,

lines 34-36), and that the computerized 3D model is generated by using CAD (col. 5, lines 30-36).

27. Regarding **claims 30 and 31**, D'Urso additionally teaches that a stent can be generated in the form substantially in which it is to be deployed in a surgical procedure (col. 5, lines 64-65) or that a precursor to the stent could be taken instead, in which case a mold would be taken of the precursor and then the stent formed in that mold (col. 5, lines 66-67).

28. Regarding **claim 36**, D'Urso teaches that these method steps are applicable to all types of implants, and does specifically include vascular implants (col. 9, lines 54-60) and can be used to make a stent as disclosed by Sirhan et al.

29. Noting that the aforementioned methods for producing an implant that morphologically matches the morphological profile are all commonly known methods. Therefore it would have been obvious to employ these methods to create the stent of Sirhan.

30. **Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over D'Urso (US 6,112,109) in view of Nakayama et al (US 2006/0036311).**

31. D'Urso discloses the method substantially as claimed including a method of manufacturing a stent for morphologically fitting a blood vessel by the steps of producing a 3D computerized model from a scanned image of the blood vessel and rapid prototyping the computerized 3D model in an appropriate material to provide the stent or a mold for the stent or a precursor thereof for morphologically matching the blood vessel (col. 6, lines 33-54 and col. 9, lines 48-60), that the

scanned image is obtained by either MRI, MRA, X-ray CT, or 3D pulsed Doppler (col. 5, lines 34-36), and that the computerized 3D model is generated by using CAD (col. 5, lines 30-36). D'Urso fails to disclose that the shell of the stent is machined to provide perforations. However, Nakayama teaches a method wherein the shell is mounted in a computer numerically controlled machine having multiple axes control and is machined to provide appropriate perforations to accommodate the subsidiary blood vessels (par. 93 and claim 22). Machining the perforations allows precise control in the manufacturing process so that the perforations in the stent align correctly with the subsidiary blood vessels, thus providing a morphologically correct fit. Since it has been held use of known technique to a known device ready for improvement to yield predictable results is old and well known in the art, therefore it would have been obvious to one of ordinary skill in the art to use the method of making the perforations in a stent as disclosed by Nakayama to make the device of D'Urso.

32. **Claims 32 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over D'Urso (US 6,112,109) in view of Phillips et al (US 6,899,728).**

33. D'Urso discloses the method substantially as claimed including a method of manufacturing a stent for morphologically fitting a blood vessel by the steps of producing a 3D computerized model from a scanned image of the blood vessel and rapid prototyping the computerized 3D model in an appropriate material to provide the stent or a mold for the stent or a precursor thereof for morphologically matching the blood vessel (col. 6, lines 33-54 and col. 9, lines 48-60), that the

scanned image is obtained by either MRI, MRA, X-ray CT, or 3D pulsed Doppler (col. 5, lines 34-36), and that the computerized 3D model is generated by using CAD (col. 5, lines 30-36). D'Urso fails to disclose that the stent is produced by embroidering the 3D image onto at least one 2D substrate element. However, Phillips discloses a method of embroidering a reinforcing wire on a 2D substrate element and the substrate is subsequently rolled into to tubular shape (see Abstract and Entire reference). Apparently the reinforcing wire provides the stent from collapsing. Since it has been held use of known technique to a known device ready for improvement to yield predictable results is old and well known in the art, therefore it would have been obvious to one of ordinary skill in the art to use the method of embroidering a reinforcing wire to the stent as disclosed by Phillips to make the device of D'Urso so that it too would have the same advantage.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tuan V. Nguyen whose telephone number is 571-272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/T. V. N./
Examiner, Art Unit 3731

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731